

EXHIBIT A

Page 1

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

4 : MDL NO. 2875
5 IN RE: VALSARTAN, :
6 LOSARTAN, AND IRBESARTAN :
7 PRODUCTS LIABILITY :
8 LITIGATION : VIDEOTAPED DEPOSITION
9 : UPON
10 : ORAL EXAMINATION
11 : OF
12 : STEPHEN S. HECHT, PhD
13 ----- X

14 TRANSCRIPT of the stenographic notes of
15 the proceedings in the above-entitled matter, as
16 taken by and before ELLEN J. GODINO, CCR, RPR, CRCR,
17 held via ZOOM VIDEOCONFERENCE from various locations,
18 with the witness located at 2231 6th Street,
19 Minneapolis, Minnesota, on Friday, January 13, 2023,
20 commencing at 8:18 a.m. Central Time.
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23
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25

1 Q. To whom are they describing the change
2 in the process? Are they describing the change in
3 the process to the FDA? Is that one of the purposes
4 of this document?

5 A. I do not think so.

6 Q. Okay. It's an amendment to the Drug
7 Master File. Correct?

8 A. Yes.

9 Q. And that gets submitted for a change to
10 FDA. Correct?

11 A. Okay, I guess that's right.

12 Q. Okay. And you say you guess that's
13 right, because you're -- fair to say, you're not
14 really an expert in regulatory or FDA issues. Is
15 that fair?

16 A. Yes, that's correct.

17 Q. Okay.

18 MR. BERNARDO: Let's take a look at Page
19 Number 2 of 16.

20 Q. So the new process changed triethylamine
21 hydrochloride salt to zinc chloride for the tetrazole
22 formation. Is that correct?

23 A. Yes.

24 Q. And that change was to reduce -- and
25 again, I'm sorry for my pronunciation, Dr. Hecht --

1 MR. SLATER: Objection.

2 Q. I want to understand what you are saying
3 has been in a conference?

4 A. Not specifically --

5 MR. SLATER: One second, Doctor --

6 (Simultaneous speaking.)

7 A. No, not specifically for this process,
8 okay? I'm saying the general mechanism of formation,
9 okay? So that is the beauty of chemistry, okay? You
10 have certain reactions that will take place under
11 certain conditions, and it doesn't matter whether
12 that's in a food product or a pharmaceutical product,
13 or in the environment. Okay? We can predict that
14 that reaction will take place.

15 And the formation of dimethylnitrosamine
16 from dimethylamine has been known for decades.

17 Q. Okay. I want to go back to your report
18 for a moment, and we're going to put on the screen,
19 page 20. And I want to have you take a look; it's
20 about five, six lines from the bottom.

21 "In their analyses of the product, they
22 would not have identified NDMA in the chromatograms
23 unless they were specifically looking for it, because
24 the peaks would be too small."

25 Do you see that?

1 A. Yep.

2 Q. Okay. And I understand you follow-up by
3 saying that that's not a legitimate scientific
4 excuse. I want to ask you a question.

5 Hypothetically, if ZHP was not expected
6 -- sorry. If nitrosamine formation would not be
7 expected, you'd -- you agree, there's no reason they
8 should have detected it in their products with the
9 testing that was done. Correct?

10 MR. SLATER: Objection.

11 (Simultaneous speaking.)

12 MR. SLATER: That doesn't make sense.

13 A. They wouldn't have seen it. Not in
14 routine testing.

15 Q. Okay. And now you say ZHP should have
16 been testing its API for both NDMA and NDEA. Is that
17 correct?

18 A. Yes.

19 Q. Is it your opinion that ZHP should have
20 been testing for all nitrosamines, or just those two?

21 A. Well, those would be -- those would be
22 the main two. But I mean, again, they're adding
23 nitrite at pH 3; this is like perfect conditions for
24 nitrosamine formation. You can read it in the
25 literature. It's been known since the 1950s, all

1 other?

2 A. No, I don't know.

3 Q. Do you have any reason to dispute that
4 Novartis conducted testing on valsartan API, prior to
5 2018?

6 A. I don't know.

7 Q. Okay. Hypothetically --

8 A. I don't know whether they did or they
9 didn't. That's my answer.

10 Q. Hypothetically -- understood.
11 Hypothetically, if Novartis did conduct testing on
12 valsartan API prior to May 2018, and did not find
13 NDMA, would that factor into your consideration and
14 the forming of your opinion?

15 A. No, because in order to find NDMA in the
16 testing, you need to be looking for it. All right?
17 The peaks -- the NDMA peak would be too small for it
18 to stand out. That's why some of these companies
19 missed it, because they looked at the solvents, the
20 ones we were just talking about. They're going to be
21 like relatively larger peaks. The NDMA peak is going
22 to be very small.

23 So you wouldn't see it. You wouldn't
24 notice it unless you were actually looking for it.
25 And that's why only Novartis figured it out, because

1 formation of -- let me start with impurities in
2 pharmaceuticals?

3 A. Not in pharmaceuticals. I mean --

4 Q. Yeah, I'm purely asking about
5 pharmaceuticals?

6 A. We did do a study on dishwashing
7 liquids. And of course, we've done a lot on tobacco,
8 but we haven't done pharmaceuticals.

9 Q. And you've never performed any
10 evaluation of a manufacturer's compliance with CGMP
11 manufacturing practices with respect to
12 pharmaceuticals. Is that fair?

13 A. Yes, correct.

14 Q. And you've never conducted testing of
15 any kind for a pharmaceutical company of any of its
16 products. Is that correct?

17 A. Correct.

18 Q. And you've never conducted an assessment
19 of a pharmaceutical product. Correct?

20 A. What do you mean by "assessment"?

21 Q. Well, I was going to use risk
22 assessment, but you didn't like that phrase earlier?

23 A. No.

24 Q. You've never studied a pharmaceutical,
25 previously to this case, to determine what risks the

1 pharmaceutical might present. Is that fair?

2 A. Correct.

3 Q. Okay. And you have no experience with
4 respect to pharmaceutical regulation and enforcement.
5 Fair?

6 A. Correct.

7 Q. And outside of litigation, you've never
8 reviewed any pharmaceutical regulatory filings.
9 Correct?

10 A. Correct.

11 Q. Okay.

12 MR. BERNARDO: And this is where the
13 word comes up, Adam.

14 Q. You're not an epidemiologist. Is that
15 fair?

16 A. I'm not what?

17 Q. An epidemiologist?

18 A. That's correct; I'm not an
19 epidemiologist.

20 Q. And therefore, you don't consider
21 yourself to be an expert in the field of
22 epidemiology. Correct?

23 A. That's correct.

24 Q. When was the last time you taught a
25 full-time university course, Dr. Hecht?

1 included on the list of supplemental materials
2 reviewed. Correct?

3 A. Right.

4 Q. And Dr. Hecht, turning now back to your
5 July report, there is an exhibit that has a similar
6 list of the materials that you reviewed. I believe
7 it's Exhibit -- I believe it's Exhibit 2 to your
8 July 7, 2021 report. If you could go ahead and take
9 a look at that.

10 A. Which exhibit is it?

11 Q. It's Exhibit 2?

12 A. All right.

13 Q. And I believe it's unnumbered.

14 A. Okay. "Documents Reviewed."

15 Q. And there's a header --

16 A. What's your question?

17 Q. Sure. I just want to confirm: There's
18 a header for ZHP documents again, and that goes on
19 until the third page --

20 A. Right.

21 Q. -- of this exhibit. Then there are
22 Hetero and Mylan documents?

23 A. Right.

24 Q. And then there's a list of 13 Teva
25 documents. Do you see that?

1 dimethylamine could have been formed from DMF, and,
2 you know, once he saw that, then obviously the light
3 bulb went off.

4 Q. Doctor, are you familiar with the FDA's
5 review process for approving DMFs and ANDA
6 applications?

7 A. Not very.

8 Q. So would you say you have an
9 understanding of what information in the Drug Master
10 File is or is not available to a finished-dose
11 manufacturer when they submit an ANDA?

12 A. It's not my area.

13 Q. And you haven't reviewed Teva's ANDAs
14 that were submitted in this case?

15 A. Pardon?

16 Q. Sorry. You have not reviewed the ANDA
17 files submitted by the finished-dose manufacturers,
18 Teva and Torrent, in this case, have you?

19 A. No.

20 Q. Do you have any understanding -- I
21 believe you may have already answered this, but just
22 to be clear -- do you have any opinion or
23 understanding as to what a finished-dose manufacturer
24 like Teva does or does not have access to, in the ZHP
25 DMF when they submit those ANDAs?